Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction

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Abstract: AIMS Treatment of patients with systemic cardiac implantable electronic device (CIED) infection with large lead vegetations is challenging and associated with relevant morbidity and mortality. To avoid complications from open surgical extraction, a novel approach with percutaneous aspiration of large vegetations prior to transvenous lead extraction was instituted. The results of this treatment concept were retrospectively analysed in this multicentre study. METHODS AND RESULTS One hundred and one patients [mean age 68.2 ± 13.1 (30-92) years] were treated in four centres for endovascular CIED infection with large lead vegetations. Mean lead vegetation size was 30.7 ± 13.5 mm. Two hundred and forty-seven leads were targeted for extraction (170 pacemaker leads, 77 implantable cardioverter-defibrillator leads). Mean lead implant duration was 81.7 (1-254) months. The transcatheter aspiration system with a specialized long venous drainage cannula and a funnel-shaped tip was based on a veno-venous extracorporeal circuit with an in-line filter. The aspiration of vegetations showed complete procedural success in 94.0% (n = 95), partial success in 5.0% (n = 5). Three major complications (3.0%) were encountered. Complete procedural success (per lead) of the subsequently performed transvenous lead extraction procedure was 99.2% (n = 245). Thirty-day mortality was 3.0% (n = 3). Five patients (5.0%) died in the further course on Days 51, 54, 68, 134, and 182 post-procedure (septic complications: n = 4; heart failure: n = 1). CONCLUSION The percutaneous aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior and during the lead extraction procedure may avoid septic embolization into the pulmonary circulation. This may potentially lead to a long-term survival benefit.

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Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction

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Aims Treatment of patients with systemic cardiac implantable electronic device (CIED) infection with large lead vegetations is challenging and associated with relevant morbidity and mortality. To avoid complications from open surgical extraction, a novel approach with percutaneous aspiration of large vegetations prior to transvenous lead extraction was instituted. The results of this treatment concept were retrospectively analysed in this multicentre study.

Methods and results One hundred and one patients [mean age 68.2 ± 13.1 (30–92) years] were treated in four centres for endovascular CIED infection with large lead vegetations. Mean lead vegetation size was 30.7 ± 13.5 mm. Two hundred and forty-seven leads were targeted for extraction (170 pacemaker leads, 77 implantable cardioverter-defibrillator leads). Mean lead implant duration was 81.7 (1–254) months. The transcatheter aspiration system with a specialized long venous drainage cannula and a funnel-shaped tip was based on a veno-venous extracorporeal circuit with an in-line filter. The aspiration of vegetations showed complete procedural success in 94.0% ($n = 95$), partial success in 5.0% ($n = 5$). Three major complications (3.0%) were encountered. Complete procedural success (per lead) of the subsequently performed transvenous lead extraction procedure was 99.2% ($n = 245$). Thirty-day mortality was 3.0% ($n = 3$). Five patients (5.0%) died in the further course on Days 51, 54, 68, 134, and 182 post-procedure (septic complications: $n = 4$; heart failure: $n = 1$).

Conclusion The percutaneous aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior and during the lead extraction procedure may avoid septic embolization into the pulmonary circulation. This may potentially lead to a long-term survival benefit.

Keywords Cardiac implantable electronic device infection • Lead extraction • Lead vegetation • Pacemaker • Implantable cardioverter-defibrillator

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What's new?

- A novel, minimally-invasive approach to treat patients with cardiac implantable electronic device infections with large lead vegetations is described.
- The percutaneous aspiration procedure of lead vegetations, which is performed concomitant to the required transvenous lead extraction, proved to be safe and effective.

Introduction

Optimal treatment of endovascular infections of cardiac implantable electronic devices (CIEDs) remains a challenge, especially in the setting of large lead vegetations. Lead vegetation size of >20 mm in diameter is a cut-off parameter to discuss open surgical extraction as opposed to transvenous lead extraction.[1] The 2015 ESC/EACTS guidelines on infective endocarditis refer to surgical extraction in the setting of large lead vegetations (>20 mm) as a Class IIb indication.[2] Open surgical extraction in such situations carries a relevant risk of morbidity and mortality.[3]On the other hand, there exist case reports and case series, that report successful transvenous extraction procedures in large lead vegetations with low perioperative mortality.[4,5] In this context, it remains unclear why endovascular CIED infection carries a 1-year mortality rate of up to 30% despite state of the art treatment (complete CIED explantation and antibiotic therapy).[6] To avoid open extraction, a novel approach with percutaneous aspiration of large vegetations (defined as ≥20 mm) prior to and during transvenous lead extraction procedures was introduced.

Methods

Indication for percutaneous aspiration procedure

The indications for the described concomitant aspiration procedure in patients undergoing transvenous lead extraction procedures were defined as follows:

- Patients with systemic CIED infection with lead vegetations and a vegetation size of equal to or more than 20 mm in the longest axis measured by transoesophageal echocardiography (TOE).
- Patients with smaller vegetation size (10–20 mm) and persistent foramen ovale.

Transcatheter aspiration procedure using an extracorporeal circuit

The transcatheter aspiration system is based on an extracorporeal circuit used in a veno-venous configuration similar to an extracorporeal membrane oxygenation circuit, except it uses a filter system instead of an oxygenator (*Figure 1*). Venous access was achieved by cannulating both femoral veins. Before placement of the cannulas, heparin was administered intravenously with a target activated clotting time of >250 s. The right femoral vein was used to place a 26-Fr Gore DrySeal Sheath (Gore Medical, USA) percutaneously as access for the AngioVac drainage cannula (Angiodynamics, USA). The AngioVac cannula is a 22-Fr coil-reinforced cannula with a length of 90 cm, an expandable funnel shaped distal tip and a 20°-angulation of the tip. The expanded funnel-shaped tip improves venous drainage and the aspiration of vegetation material (*Figure 2*). To return the filtered blood, an 18-Fr FemFlex II cannula (Edwards Life Sciences, USA) was placed percutaneously via the left femoral vein. The aspiration procedure was guided by TOE and fluoroscopy, which allows for immediate monitoring of procedural success and potential intraprocedural complications.

One of the limitations of the current AngioVac cannula is its limited steerability. To overcome this issue in cases where more steerability was required, an Amplatz Gooseneck Snare, introduced via a second venous sheath in the left femoral vein, was used to grab the tip of the cannula and create a wider range of motion by a corresponding push-and-pull technique.

The aspiration was started prior to the extraction and ideally the lead vegetations were removed completely before the extraction procedure was started. It was common that residual vegetation material could not be removed with the Angiovac system prior to the extraction procedure due to tight adherence to the leads. Therefore, the aspiration was continued during the extraction procedure in all cases to eliminate all residual vegetative material, which was mobilized during the extraction procedure. In cases with very strong adherence of the vegetation to the lead, the aspiration was facilitated by the mobilization of the vegetation with the extraction sheath.

Definitions of success of the aspiration procedure

Complete procedural success of the transcatheter aspiration procedure was defined as complete removal of all vegetative material determined by TOE.

Partial success of the aspiration procedure was defined by removal of most vegetative material with a maximum portion of 30% or less of remaining vegetation.

Failure was defined any procedure which left more than 30% of vegetation *in situ*.

All patients were continuously monitored by TOE during the entire procedure to evaluate the success of the aspiration using the above described definitions and to rule out partial or complete pulmonary embolization of vegetations, while recognizing the limitations of TOE with regard to this aspect.

Transvenous lead extraction procedure

The subclavian approach was primarily chosen for lead extraction procedures. For leads that could not be extracted by simple traction, a multistep staged lead extraction approach was performed. Application of traction was performed with the help of a locking stylet (Liberator, Cook Medical, USA). Additional lead control was achieved by the application of a compression coil (One-Tie, Cook Medical, USA). In case of severe fibrotic or calcified adhesions at the site of the vessel entry below the clavicle, the Evolution Shortie RL (Cook Medical, USA) was used. To apply counterpressure or countertraction along the course of a targeted lead either a simple polypropylene extraction sheath (Byrd Dilator Sheath, Cook Medical, USA) or a rotational mechanical dilator sheath (Evolution RL, Cook Medical, USA) were used in most cases. In a small number of leads ($n = 14$), a laser sheath (SLS II, Spectranetics, USA) was used. In case of failed or impossible superior approach, a femoral approach using a snare (Needle's Eye Snare, Cook Medical, USA) was performed.

All procedures were performed in a hybrid operating room under general anaesthesia by a cardiac surgeon ($n = 100$) or a cardiologist ($n = 1$) with standby extracorporeal circulation and a perfusionist. Patients were monitored by electrocardiogram, invasive blood pressure measurement, pulse oximetry, and TOE.

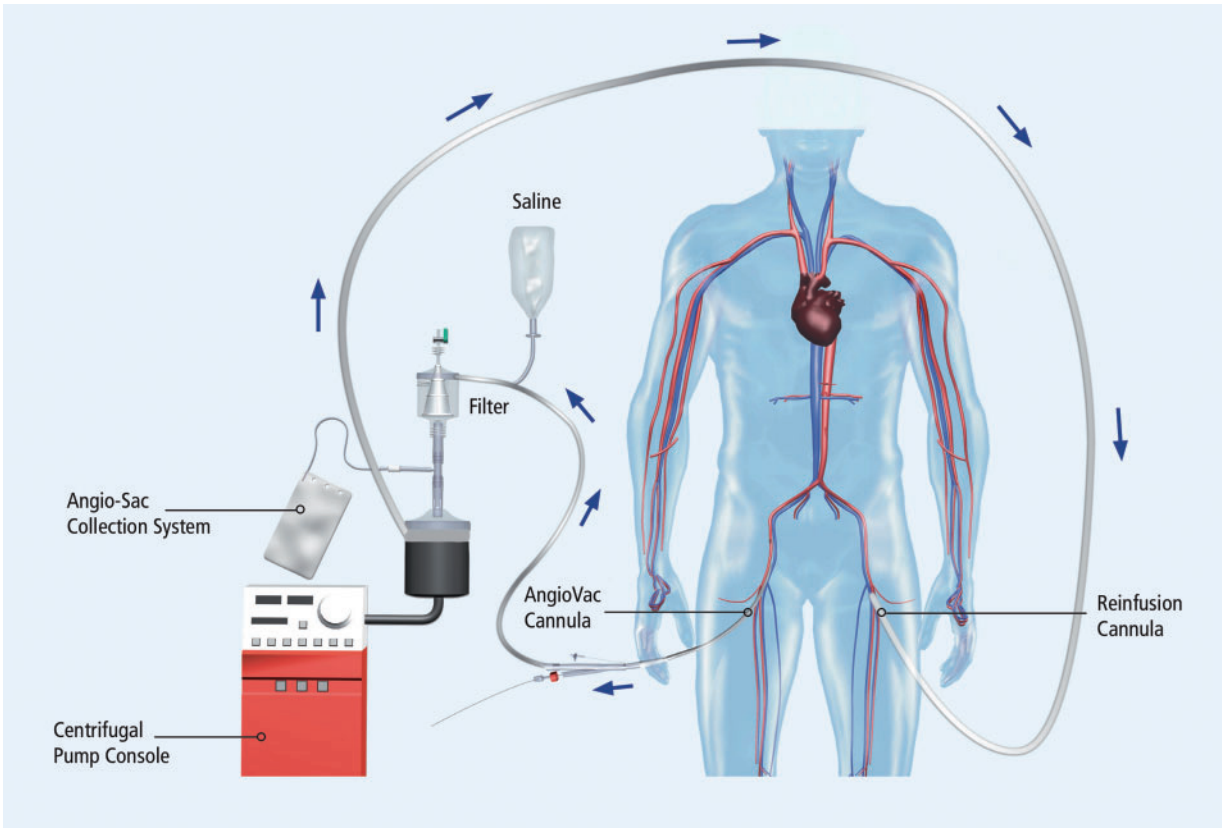

Figure 1 Percutaneous vegetation aspiration using the AngioVac system (Angiodynamics, Latham, NY, USA) relies on an extracorporeal circuit used in a veno-venous configuration incorporating a filter/bubble trap system (Photo courtesy: Angiodynamics, Latham, NY, USA).

Success was defined either as clinical success or as complete procedural success according to the definitions of the 2017 Heart Rhythm Society expert consensus.[7]

Statistics

Categorical variables are presented as numbers and percentages. Continuous variables are presented as mean ± standard deviation or as mean and range from minimum to maximum. Differences between groups were analysed by two sample *t*-test. A *P*-value of <0.05 was considered significant.

The local review boards approved the research protocol. The results obtained were analysed retrospectively with regard to efficacy and safety.

Figure 2 The AngioVac cannula (Angiodynamics, USA) is a 22-Fr coil-reinforced cannula (length 90 cm) with an expandable funnel shaped distal tip. The expanded funnel-shaped tip improves venous drainage and the aspiration of vegetation material (Photo courtesy: Angiodynamics, Latham, NY, USA).

Results

Patient population

From July 2014 until November 2018, 101 patients [mean age 68.2 ± 13.1 (30–92) years; 71 male, 30 female] were treated for endovascular CIED infection with large lead vegetations at four high-volume lead extraction centres (German Heart Center Berlin, Germany; Providence Saint Joseph Medical Center, Burbank, CA, USA; Smidt Heart Institute, Cedars Sinai Medical Center, Los Angeles, CA, USA; and University Hospital Zurich, Zurich, Switzerland). Mean lead vegetation size determined in preoperative echocardiography was 30.7 ± 13.5 mm. The distribution of vegetations sizes were as follows: vegetation <20 mm: $n = 16$ (15.8%); ≥20 mm and <25 mm: $n = 19$ (18.8%); ≥25 mm and ≤30 mm: $n = 24$ (23.8%); >30 mm: $n = 42$ (41.6%). The minimum size of lead vegetation included was 15 mm. Most lead vegetations were found to be adhering to the lead course in the right atrium. Less frequently vegetations were found to be in

Table 1 Baseline characteristics

Number of patients	101
Mean age (years)	68.2 (30–92)
Gender	
Male	71 (70.3%)
Female	30 (29.7%)
Diabetes mellitus	29 (28.7%)
Chronic kidney disease	41 (40.6%)
Bacteria	
Methicillin-sensible *Staphylococcus aureus*	22 (21.7%)
Methicillin-resistant *Staphylococcus aureus*	9 (8.9%)
Staphylococcus epidermidis	25 (24.8%)
Other *Staphylococcus*	12 (11.9%)
Enterococcus faecium	4 (4.0%)
Escherichia coli	1 (1.0%)
Streptococcus	9 (8.9%)
Other bacteria	12 (11.9%)
Culture negative	7 (6.9%)
Number of targeted leads	247
Mean lead implant duration (months)	81.7 (1–254)
Number of targeted leads per patient	2.4 ± 1.2
Lead characteristics	
Pacemaker leads	170 (68.8%)
ICD leads (single vs. dual coil)	77 (31.2%) (28 vs. 49)
Active fixation	180 (72.9%)
Passive fixation	67 (27.1%)
Right atrial leads	80 (32.4%)
Right ventricular leads	132 (53.4%)
Left ventricular leads	35 (14.2%)
Mean lead vegetation size (mm) (preoperative TOE)	30.7 ± 13.5

This provides the patient and lead characteristic.
ICD, implantable cardioverter-defibrillator; TOE, transoesophageal echocardiography.

the superior vena cava (SVC) or in the right ventricle. In seldom cases, there was concomitant involvement of the tricuspid valve.

Blood cultures were positive in 94 patients (93.1%) [*Staphylococci* in 56 patients (55.4%)]. Blood cultures were negative in 7 patients (6.9%).

In these 101 patients 247 leads were targeted for extraction [170 pacemaker leads, 77 implantable cardioverter-defibrillator (ICD) leads]. Mean lead implant duration was 81.7 (1–254) months. *Table 1* provides the patient and lead characteristics.

Procedural outcomes-aspiration procedure

The veno-venous configuration of the extracorporeal circuit to facilitate the percutaneous aspiration procedure was achieved by femoro-femoral cannulation in 98 patients. In three patients, the aspiration cannula was placed via the right internal jugular vein and the return cannula in the left femoral vein. The average perfusion time of the extracorporeal circuit was 30.2 ± 18.3 min.

The aspiration of the vegetations (*Figure 3*) showed complete procedural success in 94.0% ($n = 95$) of all cases. In one case, a highly mobile vegetation embolized into the pulmonary circulation prior to aspiration. This embolus did not result in any haemodynamic consequences and the subsequent transvenous lead extraction procedure was carried out successfully.

Three major complications related to the aspiration procedure were encountered. In one case, the right iliac vein was perforated and needed subsequent repair with a covered stent. The patient recovered uneventfully. In the second case, a patient with systemic CIED infection with large lead vegetations died intraoperatively due to refractory septic shock prior to completion of the procedure. Cannula placement was uneventful and the extracorporeal circuit of the AngioVac system worked correctly. Pericardial tamponade was ruled out in TOE. Due to severe septic shock with haemodynamic compromise despite maximal dose of vasopressors, it was regarded as highly unlikely that this event was related to the aspiration procedure, but it cannot be completely ruled out, that the aspiration procedure did not affect the outcome at all. In the third case, a patient had haemodynamic collapse shortly after initiation of the aspiration procedure and needed intraoperative resuscitation with return of spontaneous circulation in less than 2 min. The procedure was successfully completed and patient recovered uneventful without any neurologic deficiencies post-operatively. The patient was discharged on post-operative Day 2.

Procedural outcomes-concomitant transvenous lead extraction procedure

Complete procedural success (per targeted lead) of the subsequently performed transvenous lead extraction procedure was 99.2% ($n = 245$). A locking stylet (Liberator, Cook Medical, USA) was used in 64.0% ($n = 158$) and a polypropylene extraction sheath (Byrd Sheath, Cook Medical, USA) in 1.2% ($n = 3$) of all targeted leads. A mechanical rotational extraction sheath was required for the extraction of 56.7% ($n = 140$) of the leads, with the Evolution RL (Cook Medical, USA) in 139 leads and the Tightrail (Spectranetics, USA) in one lead. Fourteen leads (5.7%) were extracted with the use of a laser sheath (SLS II, Spectranetics, USA). Two major complications related to the transvenous lead extraction procedure occurred ($n = 2$; 2.0%) In both cases, severe tricuspid regurgitation resulted after the extraction of dual coil ICD leads with long lead implant durations. One patient was treated conservatively and the other patient received a biological tricuspid valve replacement. Both patients recovered well from the procedure.

Thirty-day mortality was 3.0% ($n = 3$). Further follow-up was incomplete, but the mortality that became aware to the study sites, was recorded as follows: 5 patients (5.0%) died on post-operative Days 51, 54, 68, 134, and 182 (septic complications: $n = 4$; heart failure: $n = 1$). Due to the lack of follow-up data beyond 30 days post-operatively, data are not sufficient to calculate or display mid- or long-term survival. *Table 2* gives an overview of the results.

Discussion

Cardiac implantable electronic device infections are a relevant clinical problem with a disproportional increase in relation to the rising

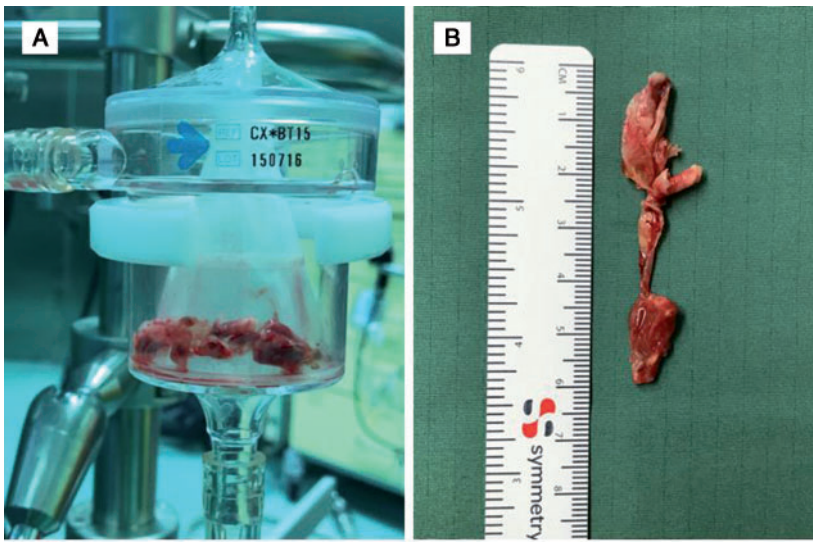

Figure 3 Result of a percutaneous aspiration procedure of vegetations using the AngioVac system.

numbers of CIED implantations.[8] The main principle of treating such infections is the complete removal of the device system, which represents a Class I indication for lead extraction.[7,9]

According to the 2015 ESC guidelines for the management of infective endocarditis, cardiac device-related infective endocarditis is a Class I indication for percutaneous extraction even in the presence of vegetations >10 mm. According to these guidelines, surgical extraction may be considered in patients with large vegetations (>20 mm), however, this is merely a Class IIb indication.[2]

Grammes *et al.*[10] reported the results of a single-centre experience in percutaneous lead extraction in 100 patients with intracardiac vegetations. Mean vegetation diameter was reported to be 1.6 cm, ranging from 0.2 to 4.0 cm. They reported no intraoperative mortality, but a 30-day mortality of 10% in this patient cohort. There exist several case reports and series reporting successful transvenous lead extraction procedures in patients with large lead vegetations.[4,5] Open surgical extraction in case of large lead vegetations becomes uncommon and has become a bail-out option nowadays. There is data showing that open surgical extraction carries a higher mortality at 1 and 12 months than percutaneous extraction procedures. The study reporting these mortality differences also showed that patients undergoing surgical extraction had a higher comorbidity index and larger vegetations, suggesting a selection bias in the reported results.[3]

There is enough evidence showing that endovascular infection of CIED systems carries a relevant long-term mortality, even though the patients were treated according to current recommendations with complete system explantation and antibiotic therapy. In the published results of the ELECTRa registry, systemic infection was identified as a predictor for increased all-cause mortality (odds ratio 4.93, 95% confidence interval 2.72–8.93; $P < 0.0001$).[11] Tarakji *et al.*[6] reported a 1-year mortality rate of 20% in patients with endovascular infection in an overall patient cohort of 502 patients with CIED infection (endovascular and pocket infection). Compared to the patients with pocket infections the mortality rate in the patients with endovascular infection was significantly higher (hazard ratio 2.1; $P = 0.0008$). However, the authors could not find a correlation between patient mortality and the presence of vegetations in the patient group with endovascular infection.[6] Greenspon *et al.*[12] showed in a group of 129 patients with lead associated endocarditis that 6-month mortality significantly increased as a function of vegetation size. Six-month mortality in patients with lead vegetations smaller than 1.0 cm was 10.1% vs. 18.4% in patients with a vegetation size of more than 1.0 cm.

Percutaneous lead extraction in patients with lead vegetations without prior aspiration of the vegetations may lead to septic emboli into the pulmonary circulation. Hypothetically, these septic emboli remaining in the pulmonary circulation may be a source for future fatal septic complications, despite accurate initial treatment. This aspect is adequately addressed by the described percutaneous aspiration procedure prior to and during the transvenous extraction procedure. As our results show the aspiration procedure using the AngioVac cannula (Angiodynamics, Latham, NY, USA) is highly effective and successful (94% complete procedural success) with a low complication risk. The addition of this procedure to the transvenous lead extraction facilitates a safe extraction procedure and avoids the need for an open surgical approach especially in cases with large lead vegetations and a high risk for septic embolizations into the pulmonary circulation. Additionally, avoiding the surgical trauma of a thoracotomy reflects a further clinical benefit for this high-risk patient cohort.

To our knowledge, this is the largest published series using this novel percutaneous aspiration procedure in transvenous lead extractions. Early data from two of the participating institutions of this study has been published before as initial experiences. One series comprised 20 patients (Burbank, California, USA) and the other experience 35 patients (Berlin, Germany).[13,14] The findings of these two separate initial experiences are consolidated by the outcome data of this multicentre study.

It is important to mention two current restrictions in the use of the AngioVac device. The first one is the gap between device costs

Table 2 Procedural data and outcomes

Configuration extracorporeal circuit	
Veno-venous	101 (100%)
Femoro-femoral	98 (97.0%)
Right internal jugular-femoral	3 (3.0%)
Mean heparin dose per patient (IU)	17 296 (3000–40 000)
Mean intraoperative ACT (s)	379.8 (172–917)
Mean extracorporeal circuit perfusion time (min)	30.2 ± 18.3
Outcome percutaneous aspiration procedure	
Complete procedural success	95 (94.0%)
Partial success	5 (5.0%)
Failure	1 (1.0%)
Major complications (device related)	3 (3.0%)
Extraction devices	
No extraction tools used	38 (15.4%)
Locking stylet	158 (64.0%)
Compression coil	149 (60.3%)
Polypropylene extraction sheath	3 (1.2%)
Powered rotational extraction sheath	140 (56.7%)
Evolution RL (Cook Medical, USA)	139 (56.3%)
Tightrail (Spectranetics, USA)	1 (0.4%)
Laser sheath (Spectranetics, USA)	14 (5.7%)
Femoral/internal jugular snare	13 (5.3%)
Outcome TLE procedure	
Complete procedural success (leads)	245 (99.2%)
Clinical success (leads)	247 (100%)
TLE related major complications (patients)	2 (2.0%) (2 TLE related high grade TR)
Mortality	
30-day mortality	3 (3.0%)

This gives an overview of all the results.
ACT, activated clotting time; TLE, transvenous lead extraction; TR, tricuspid regurgitation.

and missing specific or inadequate reimbursement of the procedure. Elimination of this gap by adjusting reimbursement and/or device costs are highly desirable to create options for a wider clinical use. The second restriction is missing familiarity of electrophysiologists or cardiologists in the use of a veno-venous extracorporeal circuit.

Limitations of the study

The current study has a few limitations, which need to be outlined. Specifically, data were collected retrospectively with a relatively small number of patients. Moreover, the results obtained from this study can only be viewed as hypothesis generating and should be validated by a larger prospective randomized trial. Furthermore, the lack of evaluating the presence or extent of septic embolism by computed tomography scan, or ideally by FDG/PET-CT scan, pre- and post-operatively is a shortcoming of the described study. Especially, this aspect is an important topic that needs to be investigated in future prospective studies.

Conclusions

In summary, the presented percutaneous aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior to and during the lead extraction procedure avoids septic embolization into the pulmonary circulation and potentially based on this mechanism leads to a survival benefit.

Conflict of interest: C.T.S. and R.H.M.S. are paid consultants for AngioDynamics, Inc. in the area of Vascular Interventions and Therapies. C.T.S. and R.H.M.S. are paid consultants for Cook Medical in the area of Lead Management. C.T.S. and T.D. have received consultant honoraria from Liva Nova. C.T.S. has received consultant honoraria from Spectranetics. All other authors report no conflict of interest with regard to this article.

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